ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 2, 2016

ClinicalTrials.gov ID: NCT00410384

Study Identification

Unique Protocol ID:	HGS1006-C1056
Brief Title:	A Study of Belimumab in Subjects With Systemic Lupus Erythematosus (BLISS-76)
Official Title:	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, 76-Week Study to Evaluate the Efficacy and Safety of Belimumab (HGS1006, LymphoStat-B™), a Fully Human Monoclonal Anti-BLyS Antibody, in Subjects With Systemic Lupus Erythematosus (SLE)
Secondary IDs:	BLISS-76 110751 [GSK]

Study Status

Record Verification:	December 2016
Overall Status:	Completed
Study Start:	December 2006 []
Primary Completion:	September 2009 [Actual]
Study Completion:	March 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Human Genome Sciences Inc.
Responsible Party:	Sponsor
Collaborators:	GlaxoSmithKline

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 9970 Serial Number: 0137 Has Expanded Access: No
Human Subjects Review:	Board Status: Approved Approval Number: 07-0143-0 Board Name: Schulman Associates Institutional Review, Inc. Board Affiliation: independent Phone: 513-761-4100 Email: GGrote@sairb.com Address: 4290 Glendale-Milford Road Cincinnati, OH 45242
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	The purpose of this study is to evaluate the efficacy, safety, tolerability, and impact on quality of life of two different doses of belimumab administered in addition to standard therapy in subjects with active, autoantibody-positive systemic lupus erythematosus (SLE) disease.
Detailed Description:	

Conditions

Conditions:	Systemic Lupus Erythematosus
Keywords:	Antibodies Autoimmune Diseases

Systemic Lupus Erythematosus
SLE
Belimumab
Lupus

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double (Participant, Investigator)
Allocation:	Randomized
Enrollment:	819 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Placebo Placebo	Drug: Placebo Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks. Other Names: • Placebo
Experimental: Belimumab 1 mg/kg Belimumab 1 mg/kg	Drug: Belimumab 1 mg/kg Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks. Other Names: • LymphoStat-B™ • belimumab
Experimental: Belimumab 10 mg/kg Belimumab 10 mg/kg	Drug: Belimumab 10 mg/kg Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks. Other Names:

Arms	Assigned Interventions
	• LymphoStat-B™ • belimumab

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

- Clinical diagnosis of SLE by ACR criteria.
- Active SLE disease.
- Autoantibody-positive.
- On stable SLE treatment regimen.

Key Exclusion Criteria:

- Pregnant or nursing
- Have received treatment with any B cell targeted therapy.
- Have received treatment with a biological investigational agent in the past year.
- Have received IV cyclophosphamide within 180 days of Day 0.
- Have severe lupus kidney disease.
- Have active central nervous system (CNS) lupus.
- Have required management of acute or chronic infections within the past 60 days.
- Have current drug or alcohol abuse or dependence.
- Have a historically positive test or test positive at screening for HIV, hepatitis B, or hepatitis C.

Contacts/Locations

Central Contact Person: US GSK Clinical Trials Call Center
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Central Contact Backup:

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IPDSharing

Plan to Share IPD: Yes
Patient-level data for this study will be made available through www.clinicalstudydatarequest.com following the timelines and process described on this site.

Supporting Information:

Time Frame:

Access Criteria:
URL:

References

Citations:

Links: URL: https://www.clinicalstudydatarequest.com
Description Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research.

Available IPD/Information: Type: Statistical Analysis Plan
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Type: Other [Annotated Case Report Form]
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Type: Study Protocol
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Type: Individual Participant Data Set
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Type: Other [Dataset Specification]
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Type: Clinical Study Report
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Type: Informed Consent Form
URL: https://www.clinicalstudydatarequest.com
Identifier: HGS1006-C1056
For additional information about this study please refer to the GSK Clinical Study Register

Delayed Results

Delay Type	Certify Initial Approval
Intervention Name(s)	belimumab

Study Results

Participant Flow

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Overall Study

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Started	275	271	273
Completed	186	199	191
Not Completed	89	72	82
Withdrawal by Subject	28	17	20
Adverse Event	23	18	23
Lack of Efficacy	20	12	17
Lack of Compliance	2	2	2

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Lost to Follow-up	4	6	6
Protocol Violation	6	6	6
Physician Decision	3	3	4
Other	3	8	4

Baseline Characteristics

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Baseline Measures

		Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg	Total
Overall Number of Participants		275	271	273	819
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	275 participants	271 participants	273 participants	819 participants
		40.0 (11.9)	40.0 (11.4)	40.5 (11.1)	40.2 (11.5)
Age, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	275 participants	271 participants	273 participants	819 participants
≤ 45 years		189	184	178	551
Between 45 and 65 years		77	83	92	252

		Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg	Total
≥ 65 years		9	4	3	16
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	275 participants	271 participants	273 participants	819 participants
	Female	252 91.64%	253 93.36%	259 94.87%	764 93.28%
	Male	23 8.36%	18 6.64%	14 5.13%	55 6.72%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	275 participants	271 participants	273 participants	819 participants
North America		145	155	136	436
Europe		100	90	105	295
Central America		30	26	32	88

Outcome Measures

1. Primary Outcome Measure:

Measure Title	SLE Responder Index (SRI) Response Rate at Week 52
Measure Description	Percentage of subjects with a ≥ 4 point reduction from baseline in SELENA SLEDAI score, and no worsening (increase of < 0.30 points from baseline) in PGA, and no new BILAG A organ domain score or 2 new BILAG B organ domain scores compared with baseline. SELENA SLEDAI is calculated from 24 individual descriptors; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare. PGA is a visual analog scale scored from 0 to 3 (1=mild, 2=moderate, 3=severe). BILAG uses a single score for each of the 8 organ domains; range is from severe to no disease (A to E).
Time Frame	Baseline, 52 Weeks

Analysis Population Description

Analysis was performed on a modified intention-to-treat (MITT) population, defined as all subjects who were randomized and received at least 1 dose of study agent. Subjects who required rescue SLE medications were declared nonresponders, as were subjects who dropped out or were missing Week 52 data.

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	275	271	273
SLE Responder Index (SRI) Response Rate at Week 52 Measure Type: Number Unit of measure: Percentage of participants	33.5	40.6	43.2

Statistical Analysis 1 for SLE Responder Index (SRI) Response Rate at Week 52

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 10 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0167
	Comments	For the primary analysis of the primary efficacy endpoint, a step-down sequential testing procedure was used to control the type 1 error.
	Method	Regression, Logistic
	Comments	Adjusted for baseline stratification factors (SELENA SLEDAI Score: ≤9 vs ≥10; proteinuria: <2g vs ≥2g per 24hr; Race: African/indig-American vs Other)

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.54
	Confidence Interval	(2-Sided) 95% 1.08 to 2.19

	Estimation Comments	[Not specified]

Statistical Analysis 2 for SLE Responder Index (SRI) Response Rate at Week 52

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 1 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0889
	Comments	After superiority of 10 mg/kg vs placebo was established, the 1 mg/kg group was tested vs placebo (2-sided alpha=0.05)
	Method	Regression, Logistic
	Comments	Adjusted for baseline stratification factors.

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.36
	Confidence Interval	(2-Sided) 95% 0.95 to 1.94
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	SRI Response Rate at Week 76
Measure Description	Percentage of subjects with a ≥ 4 point reduction from baseline in SELENA SLEDAI score, and no worsening (increase of < 0.30 points from baseline) in PGA, and no new BILAG A organ domain score or 2 new BILAG B organ domain scores compared with baseline. SELENA SLEDAI is calculated from 24 individual descriptors; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare. PGA is a visual analog scale scored from 0 to 3 (1=mild, 2=moderate, 3=severe). BILAG uses a single score for each of the 8 organ domains; range is from severe to no disease (A to E).
Time Frame	Baseline, 76 Weeks

Analysis Population Description

Analysis was performed on a MITT population, defined as all subjects who were randomized and received at least 1 dose of study agent. Subjects who required rescue SLE medications were declared nonresponders, as were subjects who dropped out or were missing Week 76 data.

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	275	271	273
SRI Response Rate at Week 76 Measure Type: Number Unit of measure: Percentage of participants	32.4	39.1	38.5

Statistical Analysis 1 for SRI Response Rate at Week 76

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 10 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1323
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	Analysis was adjusted for baseline stratification factors.

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.31
	Confidence Interval	(2-Sided) 95% 0.92 to 1.87
	Estimation Comments	[Not specified]

Statistical Analysis 2 for SRI Response Rate at Week 76

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 1 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1050
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.34
	Confidence Interval	(2-Sided) 95% 0.94 to 1.91
	Estimation Comments	Analysis was adjusted for baseline stratification factors.

3. Secondary Outcome Measure:

Measure Title	Percent of Subjects With a ≥ 4 Point Reduction From Baseline in SELENA SLEDAI Score at Week 52.
Measure Description	
Time Frame	Baseline, 52 Weeks

Analysis Population Description

Analysis was performed on a MITT population, defined as all subjects who were randomized and received at least 1 dose of study agent.

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	275	271	273
Percent of Subjects With a ≥ 4 Point Reduction From Baseline in SELENA SLEDAI Score at Week 52. Measure Type: Number Unit of measure: Percentage of participants	35.3	42.8	46.5

Statistical Analysis 1 for Percent of Subjects With a ≥ 4 Point Reduction From Baseline in SELENA SLEDAI Score at Week 52.

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 10 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0063
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	Adjusted for baseline stratification factors.
Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.63
	Confidence Interval	(2-Sided) 95% 1.15 to 2.32
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Percent of Subjects With a ≥ 4 Point Reduction From Baseline in SELENA SLEDAI Score at Week 52.

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 1 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0740
	Comments	[Not specified]

	Method	Regression, Logistic
	Comments	Adjusted for baseline stratification factors.

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.38
	Confidence Interval	(2-Sided) 95% 0.97 to 1.96
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Mean Change in Physician's Global Assessment (PGA) at Week 24.
Measure Description	The PGA is a visual analog scale scored from 0 to 3. A score of 1 corresponds to mild lupus disease activity. A score of 2 correlates with moderate disease activity and a score of 3 with severe disease activity.
Time Frame	Baseline, 24 Weeks

Analysis Population Description

Analysis was performed on a MITT population, defined as all subjects who were randomized and received at least 1 dose of study agent.

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	275	271	273
Mean Change in Physician's Global Assessment (PGA) at Week 24. Mean (Standard Error) Unit of measure: Scores on a 3-point scale	-0.49 (0.04)	-0.47 (0.04)	-0.44 (0.03)

Statistical Analysis 1 for Mean Change in Physician's Global Assessment (PGA) at Week 24.

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 10 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7962
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Adjusted for baseline PGA and baseline stratification factors.

Statistical Analysis 2 for Mean Change in Physician's Global Assessment (PGA) at Week 24.

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 1 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9703
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Adjusted for baseline PGA and baseline stratification factors.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Medical Outcomes 36-Item Short Form Health Survey (SF-36) Physical Component Summary Score (PCS) at Week 24.
Measure Description	The SF-36 is a generic health related quality of life (HRQOL) measurement. The survey includes 36 questions grouped to 8 domains and 2 summary measures (physical and mental health component, PCS and MCS, respectively) assessing HRQOL. Responses are scored according to the SF-36v2™ manual. A score is calculated for each SF-36 domain based on the patient’s response to each question within it. This is then transformed to a scale ranging from 0 (worst) to 100 (best) points. The PCS is norm-based where the mean=50 and standard deviation (SD)=10. Higher scores represent better physical health.
Time Frame	Baseline, 24 Weeks

Analysis Population Description

Analysis was performed on a MITT population, defined as all subjects who were randomized and received at least 1 dose of study agent.

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	275	271	273
Mean Change From Baseline in Medical Outcomes 36-Item Short Form Health Survey (SF-36) Physical Component Summary Score (PCS) at Week 24. Mean (Standard Error) Unit of measure: Scores on a scale	3.35 (0.51)	3.78 (0.46)	3.21 (0.43)

Statistical Analysis 1 for Mean Change From Baseline in Medical Outcomes 36-Item Short Form Health Survey (SF-36) Physical Component Summary Score (PCS) at Week 24.

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 10 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6583
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Analysis adjusted for baseline PCS and baseline stratification factors.

Statistical Analysis 2 for Mean Change From Baseline in Medical Outcomes 36-Item Short Form Health Survey (SF-36) Physical Component Summary Score (PCS) at Week 24.

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 1 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3762
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Analysis adjusted for baseline PCS and baseline stratification factors.

6. Secondary Outcome Measure:

Measure Title	Percent of Subjects Whose Average Prednisone Dose Has Been Reduced by ≥ 25% From Baseline to ≤ 7.5 mg/Day During Weeks 40 Through 52
Measure Description	
Time Frame	Baseline, Weeks 40-52

Analysis Population Description

Analysis was performed on a MITT population, defined as all subjects who were randomized and received at least 1 dose of study agent. Includes only subjects with baseline prednisone dose > 7.5 mg/day.

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	126	130	120

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Percent of Subjects Whose Average Prednisone Dose Has Been Reduced by ≥ 25% From Baseline to ≤ 7.5 mg/Day During Weeks 40 Through 52 Measure Type: Number Unit of measure: Percentage of participants	12.7	19.2	17.5

Statistical Analysis 1 for Percent of Subjects Whose Average Prednisone Dose Has Been Reduced by ≥ 25% From Baseline to ≤ 7.5 mg/Day During Weeks 40 Through 52

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 10 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4253
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	Analysis was adjusted for baseline prednisone dose and baseline stratification factors.

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.34
	Confidence Interval	(2-Sided) 95% 0.65 to 2.74
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Percent of Subjects Whose Average Prednisone Dose Has Been Reduced by ≥ 25% From Baseline to ≤ 7.5 mg/Day During Weeks 40 Through 52

Statistical Analysis Overview	Comparison Group Selection	Placebo, Belimumab 1 mg/kg
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2081
	Comments	[Not specified]

	Method	Regression, Logistic
	Comments	Analysis was adjusted for baseline prednisone dose and baseline stratification factors.

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	1.56
	Confidence Interval	(2-Sided) 95% 0.78 to 3.13
	Estimation Comments	[Not specified]

7. Other Pre-specified Outcome Measure:

Measure Title	Adverse Event (AE) Overview
Measure Description	SEE ALSO ADVERSE EVENT RESULTS SECTION
Time Frame	Up to 80 Weeks

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

Measured Values

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Overall Number of Participants Analyzed	275	271	273
Adverse Event (AE) Overview Measure Type: Number Unit of measure: Percentage of participants			
Percent of patients with at least 1 AE	92.0	93.4	92.7
Percent of patients with at least 1 Serious AE	19.6	23.2	22.3

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
Percent of patients with an AE resulting in death	0.0	0.7	0.4

Reported Adverse Events

Time Frame	Up to 80 weeks
Adverse Event Reporting Description	Includes AEs reported in patients from first dose of study agent throughout the study up to the Week 76/Exit visit or 8 weeks following the last dose of study agent for patients who withdrew from this study or decided not to participate in the optional continuation protocol (HGS1006-C1066/NCT00724867 or HGS 1006-C1074/NCT00712933).

Reporting Groups

	Description
Placebo	Placebo IV plus standard therapy; placebo administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 1 mg/kg	Belimumab 1 mg/kg IV plus standard therapy; belimumab 1 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.
Belimumab 10 mg/kg	Belimumab 10 mg/kg IV plus standard therapy; belimumab 10 mg/kg administered on Days 0, 14, 28, and every 28 days thereafter through 72 weeks.

All-Cause Mortality

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/	/

Serious Adverse Events

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	54/275 (19.64%)	63/271 (23.25%)	61/273 (22.34%)
Blood and lymphatic system disorders			
Anaemia [A] *	2/275 (0.73%)	2/271 (0.74%)	4/273 (1.47%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Febrile neutropenia [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Haemolytic anaemia [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Leukopenia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Lymphopenia [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Neutropenia [A] *	1/275 (0.36%)	1/271 (0.37%)	1/273 (0.37%)
Spontaneous haematoma [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Thrombocytopenia [A] *	2/275 (0.73%)	1/271 (0.37%)	1/273 (0.37%)
Thymus enlargement [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Cardiac disorders			
Acute myocardial infarction [A] *	1/275 (0.36%)	0/271 (0%)	1/273 (0.37%)
Angina pectoris [A] *	0/275 (0%)	0/271 (0%)	2/273 (0.73%)
Atrial fibrillation [A] *	2/275 (0.73%)	0/271 (0%)	0/273 (0%)
Bradyarrhythmia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Bradycardia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Cardiac arrest [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Cardiac failure [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Mitral valve incompetence [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Myocardial infarction [A] *	1/275 (0.36%)	0/271 (0%)	1/273 (0.37%)
Myocardial ischaemia [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Pericardial effusion [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Pericarditis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Pericarditis lupus [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Prinzmetal angina [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Ear and labyrinth disorders			
Vertigo [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Endocrine disorders			
Hyperthyroidism [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Eye disorders			
Chorioretinopathy [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Diplopia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Gastrointestinal disorders			
Abdominal adhesions [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Abdominal pain [A] *	1/275 (0.36%)	3/271 (1.11%)	0/273 (0%)
Diarrhoea [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Erosive oesophagitis [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Food poisoning [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Gastric ulcer [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Gastritis [A] *	2/275 (0.73%)	0/271 (0%)	0/273 (0%)
Gastrointestinal haemorrhage [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Gastrointestinal inflammation [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Haematemesis [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Ileus [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Intestinal haemorrhage [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Intestinal obstruction [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Lower gastrointestinal haemorrhage [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nausea [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Pancreatitis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Pancreatitis acute [A] *	2/275 (0.73%)	0/271 (0%)	1/273 (0.37%)
Proctitis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Upper gastrointestinal haemorrhage [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Varices oesophageal [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Vomiting [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
General disorders			
Chest discomfort [A] *	1/275 (0.36%)	0/271 (0%)	1/273 (0.37%)
Chills [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Death [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Fatigue [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Infusion related reaction [A] *	0/275 (0%)	1/271 (0.37%)	3/273 (1.1%)
Non-cardiac chest pain [A] *	4/275 (1.45%)	0/271 (0%)	0/273 (0%)
Oedema peripheral [A] *	0/275 (0%)	0/271 (0%)	2/273 (0.73%)
Pyrexia [A] *	2/275 (0.73%)	1/271 (0.37%)	4/273 (1.47%)
Hepatobiliary disorders			
Autoimmune hepatitis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Cholecystitis [A] *	1/275 (0.36%)	2/271 (0.74%)	0/273 (0%)
Cholecystitis acute [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Cholelithiasis [A] *	3/275 (1.09%)	2/271 (0.74%)	1/273 (0.37%)
Gallbladder non-functioning [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Hepatitis toxic [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Infections and infestations			
Appendicitis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Arthritis bacterial [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Bronchitis [A] *	1/275 (0.36%)	0/271 (0%)	3/273 (1.1%)
Bronchitis bacterial [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Bursitis infective staphylococcal [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Cellulitis [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Cellulitis staphylococcal [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Disseminated cytomegaloviral infection [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Enterocolitis infectious [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Erysipelas [A] *	0/275 (0%)	2/271 (0.74%)	0/273 (0%)
Escherichia bacteraemia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Escherichia sepsis [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Fungal skin infection [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Furuncle [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Gastroenteritis [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Gastroenteritis viral [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Gastrointestinal infection [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Gastrointestinal viral infection [A] *	0/275 (0%)	2/271 (0.74%)	0/273 (0%)
Genital herpes [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
HIV infection [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Helicobacter gastritis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hepatitis B [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Herpes zoster [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Herpes zoster multi-dermatomal [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Infected bites [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Infected sebaceous cyst [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Influenza [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Lower respiratory tract infection [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Meningitis aseptic [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Oral candidiasis [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Pneumococcal sepsis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Pneumonia [A] *	4/275 (1.45%)	3/271 (1.11%)	5/273 (1.83%)
Pneumonia bacterial [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Pyelonephritis [A] *	1/275 (0.36%)	2/271 (0.74%)	0/273 (0%)
Pyelonephritis acute [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Skin candida [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Staphylococcal bacteraemia [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Staphylococcal skin infection [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Subcutaneous abscess [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Urinary tract infection [A] *	3/275 (1.09%)	3/271 (1.11%)	3/273 (1.1%)
Urosepsis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Injury, poisoning and procedural complications			
Anaemia postoperative [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Clavicle fracture [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Deep vein thrombosis postoperative [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Lumbar vertebral fracture [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Meniscus lesion [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Narcotic intoxication [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Operative haemorrhage [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Perirenal haematoma [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Post procedural haematoma [A] *	0/275 (0%)	0/271 (0%)	2/273 (0.73%)
Procedural complication [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Rib fracture [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Road traffic accident [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Ulna fracture [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Investigations			
Bacteria blood identified [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Metabolism and nutrition disorders			
Dehydration [A] *	1/275 (0.36%)	1/271 (0.37%)	1/273 (0.37%)
Hypokalaemia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Metabolic acidosis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Type 2 diabetes mellitus [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] *	1/275 (0.36%)	2/271 (0.74%)	0/273 (0%)
Back pain [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Bursitis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Costochondritis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Flank pain [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Intervertebral disc protrusion [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Musculoskeletal chest pain [A] *	2/275 (0.73%)	0/271 (0%)	0/273 (0%)
Musculoskeletal discomfort [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Myalgia [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Neck pain [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Osteoarthritis [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Osteonecrosis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Osteoporosis [A] *	1/275 (0.36%)	1/271 (0.37%)	0/273 (0%)
Pain in extremity [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Pain in jaw [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Pathological fracture [A] *	1/275 (0.36%)	2/271 (0.74%)	0/273 (0%)
Polymyositis [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
SLE arthritis [A] *	1/275 (0.36%)	1/271 (0.37%)	1/273 (0.37%)
Spinal osteoarthritis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Synovial cyst [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Synovitis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Temporomandibular joint syndrome [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign soft tissue neoplasm [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Bladder papilloma [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Breast cancer [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Carcinoid tumour of the stomach [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Cervix carcinoma stage 0 [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Lipoma [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Ovarian cancer [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Nervous system disorders			
Amnesia [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Brain stem ischaemia [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Convulsion [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Dizziness [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Headache [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Hypoaesthesia [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Intracranial hypotension [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Lupus encephalitis [A] *	1/275 (0.36%)	0/271 (0%)	1/273 (0.37%)
Mononeuropathy multiplex [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Myasthenia gravis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Myelitis transverse [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Neuritis [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Neuropsychiatric lupus [A] *	0/275 (0%)	0/271 (0%)	2/273 (0.73%)
Peripheral sensory neuropathy [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Reversible posterior leukoencephalopathy syndrome [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Ruptured cerebral aneurysm [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Subarachnoid haemorrhage [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Syncope [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Thalamic infarction [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Vasculitis cerebral [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Psychiatric disorders			
Depression [A] *	0/275 (0%)	2/271 (0.74%)	2/273 (0.73%)
Drug abuse [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Insomnia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Mania [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Renal and urinary disorders			
Cystitis noninfective [A] *	2/275 (0.73%)	0/271 (0%)	0/273 (0%)
Diabetic nephropathy [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Glomerulonephritis membranous [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Lupus nephritis [A] *	5/275 (1.82%)	2/271 (0.74%)	3/273 (1.1%)
Nephrolithiasis [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Nephrotic syndrome [A] *	0/275 (0%)	0/271 (0%)	2/273 (0.73%)
Proteinuria [A] *	1/275 (0.36%)	0/271 (0%)	2/273 (0.73%)
Renal failure acute [A] *	3/275 (1.09%)	0/271 (0%)	0/273 (0%)
Reproductive system and breast disorders			
Cervical dysplasia [A] *	1/275 (0.36%)	2/271 (0.74%)	0/273 (0%)
Cervix disorder [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Cystocele [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Menorrhagia [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Ovarian cyst [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Postmenopausal haemorrhage [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Uterovaginal prolapse [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Vaginal haemorrhage [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Asthma [A] *	1/275 (0.36%)	0/271 (0%)	1/273 (0.37%)
Dyspnoea [A] *	2/275 (0.73%)	1/271 (0.37%)	0/273 (0%)
Hypoxia [A] *	0/275 (0%)	1/271 (0.37%)	0/273 (0%)
Interstitial lung disease [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Organising pneumonia [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Pleural effusion [A] *	1/275 (0.36%)	1/271 (0.37%)	1/273 (0.37%)
Pleurisy [A] *	0/275 (0%)	0/271 (0%)	3/273 (1.1%)
Pulmonary arterial hypertension [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Pulmonary embolism [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Skin and subcutaneous tissue disorders			
Dermatitis bullous [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Hyperhidrosis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Skin necrosis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Skin ulcer [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Systemic lupus erythematosus rash [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Vascular disorders			
Deep vein thrombosis [A] *	1/275 (0.36%)	0/271 (0%)	2/273 (0.73%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Femoral artery embolism [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Hypertension [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Jugular vein thrombosis [A] *	0/275 (0%)	0/271 (0%)	1/273 (0.37%)
Raynaud's phenomenon [A] *	0/275 (0%)	1/271 (0.37%)	1/273 (0.37%)
Subclavian vein thrombosis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)
Vasculitis [A] *	1/275 (0.36%)	0/271 (0%)	0/273 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 12.0

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	213/275 (77.45%)	217/271 (80.07%)	219/273 (80.22%)
Blood and lymphatic system disorders			
Anaemia [A] *	17/275 (6.18%)	7/271 (2.58%)	7/273 (2.56%)
Gastrointestinal disorders			
Abdominal pain [A] *	15/275 (5.45%)	17/271 (6.27%)	18/273 (6.59%)
Abdominal pain upper [A] *	9/275 (3.27%)	19/271 (7.01%)	11/273 (4.03%)
Diarrhoea [A] *	28/275 (10.18%)	34/271 (12.55%)	33/273 (12.09%)
Gastrooesophageal reflux disease [A] *	6/275 (2.18%)	16/271 (5.9%)	6/273 (2.2%)
Nausea [A] *	27/275 (9.82%)	42/271 (15.5%)	45/273 (16.48%)
Vomiting [A] *	18/275 (6.55%)	18/271 (6.64%)	24/273 (8.79%)
General disorders			
Fatigue [A] *	24/275 (8.73%)	26/271 (9.59%)	21/273 (7.69%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Oedema peripheral [A] *	21/275 (7.64%)	26/271 (9.59%)	25/273 (9.16%)
Pyrexia [A] *	19/275 (6.91%)	22/271 (8.12%)	27/273 (9.89%)
Infections and infestations			
Bronchitis [A] *	20/275 (7.27%)	19/271 (7.01%)	30/273 (10.99%)
Gastroenteritis [A] *	11/275 (4%)	15/271 (5.54%)	14/273 (5.13%)
Influenza [A] *	12/275 (4.36%)	19/271 (7.01%)	8/273 (2.93%)
Nasopharyngitis [A] *	24/275 (8.73%)	29/271 (10.7%)	43/273 (15.75%)
Oral herpes [A] *	8/275 (2.91%)	15/271 (5.54%)	11/273 (4.03%)
Pharyngitis [A] *	14/275 (5.09%)	16/271 (5.9%)	16/273 (5.86%)
Sinusitis [A] *	28/275 (10.18%)	21/271 (7.75%)	31/273 (11.36%)
Upper respiratory tract infection [A] *	58/275 (21.09%)	53/271 (19.56%)	54/273 (19.78%)
Urinary tract infection [A] *	41/275 (14.91%)	50/271 (18.45%)	41/273 (15.02%)
Viral upper respiratory tract infection [A] *	12/275 (4.36%)	17/271 (6.27%)	13/273 (4.76%)
Vulvovaginal mycotic infection [A] *	15/275 (5.45%)	18/271 (6.64%)	15/273 (5.49%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] *	42/275 (15.27%)	42/271 (15.5%)	41/273 (15.02%)
Back pain [A] *	20/275 (7.27%)	25/271 (9.23%)	27/273 (9.89%)
Myalgia [A] *	21/275 (7.64%)	24/271 (8.86%)	19/273 (6.96%)
Pain in extremity [A] *	13/275 (4.73%)	12/271 (4.43%)	24/273 (8.79%)
SLE arthritis [A] *	14/275 (5.09%)	7/271 (2.58%)	9/273 (3.3%)
Nervous system disorders			
Dizziness [A] *	11/275 (4%)	14/271 (5.17%)	16/273 (5.86%)
Headache [A] *	38/275 (13.82%)	56/271 (20.66%)	43/273 (15.75%)

	Placebo	Belimumab 1 mg/kg	Belimumab 10 mg/kg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Psychiatric disorders			
Anxiety [A] *	10/275 (3.64%)	16/271 (5.9%)	6/273 (2.2%)
Depression [A] *	10/275 (3.64%)	14/271 (5.17%)	19/273 (6.96%)
Insomnia [A] *	13/275 (4.73%)	26/271 (9.59%)	17/273 (6.23%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] *	15/275 (5.45%)	21/271 (7.75%)	26/273 (9.52%)
Skin and subcutaneous tissue disorders			
Rash [A] *	12/275 (4.36%)	17/271 (6.27%)	20/273 (7.33%)
Vascular disorders			
Hypertension [A] *	20/275 (7.27%)	13/271 (4.8%)	15/273 (5.49%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 12.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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